

### **THE OFFICE ACTION**

In the Office Action issued on September 22, 2003, the Examiner rejected claims 1-3, and 6-20 under 35 U.S.C. §112, first paragraph, for scope of enablement. The Examiner also rejected claims 1-7, and 9-20 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Examiner also objected to claims 1-19 as containing minor informalities. The Examiner rejected claims 1-6, 9-13, 17 and 20 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,317,540 to Wakeman ("Wakeman"). The Examiner further rejected claims 1-10 and 20 under 35 U.S.C. §102(b) as being anticipated by DE19712565. The Examiner also rejected claims 1-20 under 35 U.S.C. §102(b) as being anticipated by WO 91/07876 to Vandevelde et al ("Vandevelde"). The Examiner also rejected claims 1-20 under 35 U.S.C. §102(b) as being anticipated DE4137544 to Harwardt et al. ("Harwardt").

### **REMARKS**

Applicants have carefully considered the Office Action issued on September 22, 2003. Applicants respectfully request reconsideration of the application in light of the above amendments and the following comments.

#### **A. Claims 1-20 Comply with 35 U.S.C. §112**

The Examiner rejected claims 1-3 and 6-20 under 35 U.S.C. §112, first paragraph, for scope of enablement as not reasonably providing enablement for treating any "diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases and disinfection." Specifically, it is the Examiner's position that a person of skill in the art would have to engage in undue experimentation to test the instant compound for treating any skin diseases. Applicants traverse for at least the following reasons.

First, the Examiner mischaracterizes the recitation of claim 1. Despite the Examiner's assertion, claim 1 does not recite that the use of of tosylchloramide(s), tosylchloramide salt(s), their derivatives, decomposition products and mixtures thereof for the treatment of ANY diseases. Indeed no such claim is made. Rather, it simply recites the use of these compounds for treatment of diseases of the skin and mucous membranes, organs and tissues without reciting specific diseases. As is well understood, claims must be read in light of the specification. Here, one skilled in the art

would be well apprised of the scope of the claims in light of the teachings of the specification and would not be required to engage in undue experimentation to practice the invention.

Second, it is accepted law "that a claim may be broader than the specific embodiment[s] disclosed in a specification" and that such an occurrence "is in itself no moment". *In re Rasmussen*, 211 USPQ 323, 326 (CCPA 1981). That is, it is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize what is being claimed. *In re Smythe*, 178 USPQ 279, 284 (CCPA 1973), *In re Wertheim*, 191 USPQ 90, 96 (CCPA 1976). Thus, the scope of protection is not necessarily limited to the specific examples described in the specification. The claim must be read and evaluated as one skilled in the art would evaluate them. The Examiner cannot expect, and the patent laws do not require, that the applicant present an exhaustive list of examples for every specific disease and condition that the present invention finds use in treating. In this respect, "[i]t is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art." *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). In the present case, therefore, applicants submit that the scope of the claims are commensurate with the scope of the disclosure and that the open-endedness of claim 1 is limited by what a person skilled in the art would understand to be workable, without the need for undue experimentation.

In addition, the specification lists additional diseases and conditions treatable according to the present invention than those specified by the Examiner. Specifically, the application recites that the treatable diseases include, "viral diseases, such as herpes genitalis: the most widely spread venereal disease, herpes simplex, herpes labialis, chickenpox: zoster varicella-virus, shingles and herpes facialis, herpes zoster, itching of the skin, such as mosquito bites and also vesicle-forming skin, mucous membrane and tissue diseases, such as neurodermatitis, psoriasis, acne, aphthae, stomatitis aphthosa and stomatitis herpetica." (page 3, paragraph 2). Also "it is possible to treat skin and mucous membrane diseases, in particular such diseases which lead or may lead to 'efflorescences'" as well as other "vesicle forming skin diseases." The benefits of the invention can be seen with respect to "all vesicle-forming, itching, viral-caused skin and mucous membrane diseases and lead to the same results – the same is true of corresponding diseases of tissue and organs." (page 7, paragraph 3). Thus, applicants submit that the present claims is not unacceptably

broad under §112.

The Examiner also rejected claims 1-7, and 9-20 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, the Examiner stated that since the recitations "their derivatives" and "decomposition products" are not defined in the specification, one of ordinary skill in the art could not interpret the metes and bounds of the claims. Applicants respectfully traverse.

The term "derivative" and "decomposition products" with respect to tosylchloramide(s) are clear and definite to a skilled artisan. Specifically, "derivative" refers to closely related chemical compounds derived tosylchloramide(s) via known reactions. Likewise, the term "decomposition products" refers to products derived from tosylchloramide(s) via well known decomposition reactions. Thus, applicants submit that claims 1-20 are sufficiently definite and distinct under 35 U.S.C. §112, second paragraph.

With respect to the Examiner's objection to the claims for minor informalities, an amendment has been made to claim 1 reciting that the compounds are applied to the area to treated.

#### **B. The Pending Claims Are Not Anticipated by Wakeman**

The Examiner rejected claims 1-6, 9-13, 17 and 20 under 35 U.S.C. §102(b) as being anticipated by Wakeman. Applicants respectfully traverse.

Wakeman is directed to the use of quaternary ammonium aromatic sulfonamides for disinfection and as bacteriostat agents (col. 3, line 13 – col. 4, line 15). In this respect, Wakeman only discloses the use of such compounds on inanimate objects. Wakeman neither discloses nor suggests a method for treating diseases by administering tosylchloramide(s), tosylchloramide salt(s), their derivatives, decomposition products and mixtures thereof. Despite the Examiner's arguments, Wakeman's method steps do not "inherently treat the instant particular skin diseases" because Wakeman does not teach applying compounds to the skin or other tissue. Thus, applicants submit that Wakeman fails to anticipate the present claims.

#### **C. The Present Claims Are Not Anticipated by DE1971256**

The Examiner rejected claims 1-10 and 20 under 35 U.S.C. §102(b) as being anticipated by DE1971256. Applicants respectfully traverse.

DE1971256 is directed to a composition containing an agent which generates Singulett-oxygene and photos, respectively, and a process for the treatment of blood and blood products with said composition. A method of treating diseases of the skin and the mucous membranes as well as organs and tissues is clearly not disclosed or suggested by DE1971256. Despite the Examiner's arguments, the DE1971256 method steps do not "inherently treat the instant particular skin diseases" because DE1971256 does not teach applying compounds to the skin or other tissue. The method steps are NOT the same as the instant method. Thus, applicants submit that DE1971256 fails to anticipate the present claims.

**D. The Present Claims Are Not Anticipated by Vandervelde**

The Examiner rejected claims 1-20 under 35 U.S.C. §102(b) as being anticipated by Vandervelde. Applicants respectfully traverse.

Vandervelde is directed to an agent which acts against retrovirus group viruses, whereby the agent consists of a chlorinated organic compound which stably and lastingly releases chlorine when in solution. In addition, Vandervelde is only disclosed as being applied to inanimate objects (see abstract) and NOT for use on skin or other tissue. Despite the Examiner's arguments, Vandervelde's method steps do not "inherently treat the instant particular skin diseases" because Vandervelde does not teach applying compounds to the skin or other tissue.

**E. The Present Claims Are Not Anticipated by Harwardt**

The Examiner rejected claims 1-20 under 35 U.S.C. §102(b) as being anticipated by Harwardt. Applicants respectfully traverse.

Harwardt is directed to the use of an oxygen generating compound as an antiseptic and for disinfection (see page 2, lines 3 and 4). Harwardt is NOT directed to a method for the treatment of diseases. As the Examiner has stated, disinfection is NOT a disease state. Harwardt has simply not disclosed or suggested a method for treating skin or other diseases. Despite the Examiner's arguments, Harwardt's method steps do not "inherently treat the instant particular skin diseases" because Harwardt does not teach the same method steps as the instant method.

**CONCLUSION**

In view of the foregoing comments, Applicants submit that claims 1-20 are in

condition for allowance. Applicants respectfully request early notification of such allowance. Should any issues remain unresolved, the Examiner is encouraged to contact the undersigned to attempt to resolve any such issues.

If any fee is due in conjunction with the filing of this response, Applicants authorize deduction of that fee from Deposit Account 06-0308.

Respectfully submitted,

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